

ORIGINAL ARTICLE

Spectrum of Cutaneous Adverse Drug Reactions in a Tertiary Care Hospital in Bangladesh

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ABSTRACT

Background: Cutaneous adverse drug reactions represent a significant clinical challenge in dermatology, encompassing a broad spectrum of morphological patterns ranging from mild exanthems to life-threatening severe cutaneous adverse reactions. Data on their spectrum in Bangladesh remain limited. **Objective:** To evaluate the clinical spectrum, causative drugs, and severity of cutaneous adverse drug reactions among hospitalized adult patients. **Methods & Materials:** This prospective cohort study was conducted at the Department of Dermatology and Venereology, Bikrampur Bhuiyan Medical College and Hospital, Munshiganj, Bangladesh from January to December 2025. A total of 47 adult patients with suspected cutaneous adverse drug reactions were enrolled using purposive sampling. Clinical patterns were documented through dermatological examination, and causality assessment was performed using the Naranjo adverse drug reaction probability scale. Data were analyzed using SPSS version 23.0. **Results:** Among 47 patients, the mean age was 42.6 ± 15.3 years, with a female predominance of 57.4% (n=27). Morbilliform exanthema was the most frequent pattern (34.0%), followed by urticarial reactions (21.3%) and fixed drug eruptions (17.0%). Stevens-Johnson syndrome and toxic epidermal necrolysis accounted for 12.8% of cases. Antibiotics were the most commonly implicated drug class (44.7%), followed by anticonvulsants (19.1%). Severe cutaneous adverse reactions were significantly associated with anticonvulsant use ($p < 0.01$). **Conclusion:** Cutaneous adverse drug reactions in Bangladeshi adults demonstrate a diverse clinical spectrum, with morbilliform exanthema being most common. Antibiotics and anticonvulsants are the leading causative agents. Prompt recognition and early withdrawal of offending drugs are crucial to reduce morbidity and mortality.

Keywords: Adverse drug reaction, Antibiotics, Drug eruptions, Exanthema, Pharmacovigilance.

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INTRODUCTION

Cutaneous adverse drug reactions (CADRs) represent a significant and increasingly recognized clinical challenge in dermatology and internal medicine [1]. These reactions encompass a broad and heterogeneous spectrum of morphological patterns that range from self-limiting mild exanthems to life-threatening severe cutaneous adverse reactions (SCARs) [2]. Skin manifestations are the most common clinical presentation of drug allergy, underscoring the critical importance of prompt identification and withdrawal of the offending agent [3]. The global burden of CADRs is substantial, with a systematic review of Indian population data reporting a pooled incidence of 9.22 per 1000 total patients among outpatient and inpatient settings [4]. Antimicrobial agents, nonsteroidal anti-inflammatory drugs (NSAIDs), and anti-epileptic drugs constitute the major causative drug classes worldwide [5]. The clinical spectrum of CADRs is remarkably diverse, with over 30 distinct morphological patterns documented in the literature [1]. Among these, morbilliform

(maculopapular) exanthema consistently emerges as the most frequently observed pattern, accounting for approximately 28–34% of all CADRs [6]. Urticarial reactions, fixed drug eruptions (FDEs), and erythema multiforme represent other commonly encountered patterns [7]. While the majority of CADRs are benign and resolve spontaneously upon drug discontinuation, a small but clinically significant proportion progress to SCARs [8]. These include Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), drug reaction with eosinophilia and systemic symptoms (DRESS), and acute generalized exanthematous pustulosis (AGEP) [9]. These severe reactions are associated with substantial morbidity and mortality; systematic reviews have reported in-hospital mortality rates ranging from 12% to 49% for SJS/TEN [10]. DRESS carries a mortality of approximately 5.7%, while AGEP mortality is reported at 3.1% [11]. Antibiotics are recognized as the most common causative agents of CADRs globally [10]. A single-center retrospective study over ten years identified cephalosporins (31.7%), penicillins (25.4%), and quinolones (19.0%) as the

most frequent antibiotic classes implicated in SCARs [10]. Anticonvulsants represent another major drug class associated with cutaneous reactions, ranging from mild maculopapular rashes to life-threatening SJS and TEN [11]. Lamotrigine, carbamazepine, and phenytoin carry the highest risk among antiseizure medications [11]. The risk of SJS/TEN following initiation of antiseizure medications is particularly elevated for lamotrigine (29.31 per 100,000 initiators) and carbamazepine, necessitating vigilant monitoring and, in certain populations, genetic screening for HLA-B 15:02 alleles [12]. In resource-limited settings, the challenge of CADR surveillance and management is further compounded by limited pharmacovigilance infrastructure and widespread self-medication [13]. Access to specialized dermatological care remains restricted in many parts of South Asia. In Bangladesh, despite a large and growing pharmaceutical market with increasing polypharmacy, systematically collected data on the clinical spectrum, causative agents, and outcomes of CADR remain sparse [3]. A five-year retrospective study from a local hospital setting in Bangladesh reported that among SCAR cases, 46% were SJS, 29% were TEN, 16% were DRESS, and 10% were AGEP. Anticonvulsants were identified as the most frequently implicated drug class in that series [3]. However, comprehensive prospective data evaluating the full spectrum of CADR—including both mild and severe reactions—among adult patients in Bangladeshi tertiary care settings is lacking [13]. Understanding the local epidemiological profile, predominant clinical patterns, and culprit drugs is essential for guiding empirical therapy, strengthening pharmacovigilance programs, and developing evidence-based preventive strategies tailored to the Bangladeshi context. Therefore, this prospective cohort study was designed to evaluate the spectrum of cutaneous adverse drug reactions among adult patients presenting to a tertiary care hospital in Dhaka, Bangladesh.

METHODS & MATERIALS

This prospective cohort study was conducted at the Department of Dermatology and Venereology, Bikrampur Bhuiyan Medical College and Hospital, Munshiganj, Bangladesh Bangladesh, over 12 months from January 2025 to December 2025. The study population comprised adult patients (aged ≥ 18 years) presenting to the dermatology outpatient department or admitted to the inpatient wards with clinically suspected cutaneous adverse drug reactions. A total of 47 patients were enrolled using purposive sampling.

Inclusion criteria: Patients were included if they were aged 18 years or older, had a clinical diagnosis of cutaneous adverse drug reaction confirmed by a consultant dermatologist, provided written informed consent, and were willing to complete the study questionnaires and undergo clinical

examination. Both newly developed reactions and those presenting with active cutaneous manifestations were eligible.

Exclusion criteria: Patients were excluded if they had pre-existing dermatological conditions mimicking drug eruptions, such as psoriasis, eczema, or viral exanthems, had received systemic immunosuppressive therapy within the preceding four weeks, were pregnant or lactating women, or had incomplete clinical records. Additionally, patients with known chronic skin disorders that could confound the diagnosis were excluded.

Study procedure: All enrolled patients underwent a comprehensive clinical evaluation conducted by a trained dermatologist. Detailed demographic data, comprehensive drug history (including all medications taken within the four weeks preceding symptom onset), and relevant clinical findings were recorded using a pre-designed, semi-structured case report form. Cutaneous examination was performed meticulously to document the morphological pattern, distribution, extent, and severity of skin lesions. Causality assessment was performed using the Naranjo adverse drug reaction probability scale, a validated and widely used tool comprising ten questions that yield a total score ranging from -4 to +13, categorizing the likelihood of an adverse drug reaction as definite (score ≥ 9), probable (5-8), possible (1-4), or doubtful (≤ 0) [14]. Clinical patterns were classified according to established dermatological criteria [1,6]. Disease severity for severe cutaneous adverse reactions was assessed using the SCORTEN (Severity-of-Illness Score for Toxic Epidermal Necrolysis) scoring system, which incorporates seven prognostic parameters to predict in-hospital mortality, with scores ranging from 0 to 7, and higher scores indicating greater mortality risk [15]. All clinical assessments and causality evaluations were performed by the same dermatologist to ensure consistency.

Data analysis: Data were entered and analyzed using SPSS for Windows, version 23.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics were computed for demographic and clinical variables; continuous data were expressed as mean $\pm$ standard deviation, while categorical variables were presented as frequencies and percentages. The association between drug classes and clinical patterns was examined using the chi-square test or Fisher's exact test, as appropriate. A p-value of less than 0.05 was considered statistically significant.

RESULT

Figure 1 shows that female participants were predominant, comprising 27 (57%), while males accounted for 20 (43%). Thus, females represented a slightly higher proportion of the study participants.

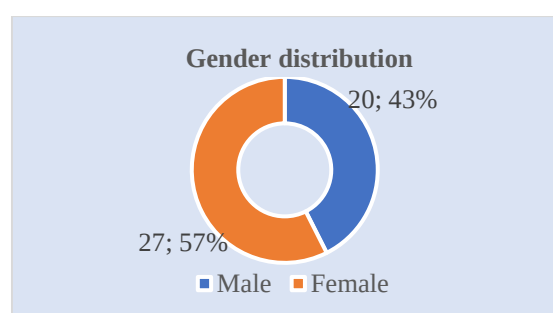


Figure 1 Gender distribution of the study participants ($n=47$).

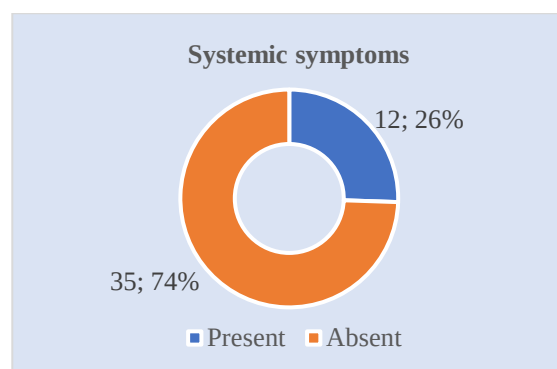


Figure 2 Presence of systemic symptoms.

Figure 2 illustrates that systemic symptoms were absent in 35 (74%) participants, while 12 (26%) participants had systemic

symptoms. Thus, the majority of participants did not report systemic symptoms.

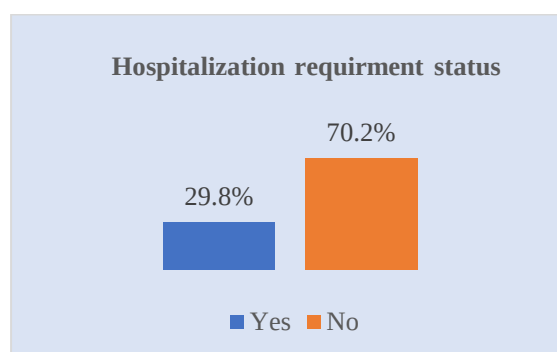


Figure 3 Hospitalization requirement status.

Figure 3 depicts that 70.2% of participants did not require hospitalization, while 29.8% required hospitalization. Thus, the majority of participants did not require hospitalization.

Table I shows that morbilliform exanthema was the most common clinical pattern of cutaneous adverse drug reactions, occurring in 16 participants (34%). This was followed by

urticarial reactions in 10 (21.3%) and fixed drug eruptions in 8 participants (17.0%). Stevens-Johnson syndrome, DRESS syndrome, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, and erythema multiforme were less frequently observed. Overall, mild-to-moderate reactions predominated over severe cutaneous adverse drug reactions.

Table I

Clinical patterns of cutaneous adverse drug reactions.

Clinical pattern	n	%
Morbilliform exanthema	16	34.0
Urticarial reactions	10	21.3
Fixed drug eruptions	8	17.0
Stevens-Johnson syndrome	4	8.5
Toxic epidermal necrolysis	2	4.3
DRESS syndrome	3	6.4
Acute generalized exanthematous pustulosis	2	4.3
Erythema multiforme	2	4.3

Table II shows that antibiotics were the most common causative drug class, implicated in 21 (44.7%) cases. This was followed by other drugs (21.3%), anticonvulsants (19.1%), and

nonsteroidal anti-inflammatory drugs (14.9%). Thus, antibiotics were the predominant drug class associated with cutaneous adverse drug reactions in this study.

Table II

Causative drug classes implicated in cutaneous adverse drug reactions.

Drug class	n	%
Antibiotics	21	44.7
Anticonvulsants	9	19.1
Nonsteroidal anti-inflammatory drugs	7	14.9
Others (antitubercular, antifungal, antihypertensive)	10	21.3

Table III shows that probable causality was the most common category, observed in 24 participants (51.1%), followed by possible causality in 17 (36.2%). Definite causality was found

in 6 (12.8%) cases, while no cases were classified as doubtful. Thus, most cutaneous adverse drug reactions were classified as probable or possible according to the Naranjo scale.

Table III

Causality assessment according to the Naranjo adverse drug reaction probability scale.

Category	Naranjo score range	n	%
Definite	≥9	6	12.8
Probable	5–8	24	51.1
Possible	1–4	17	36.2
Doubtful	≤0	0	0.0

Table IV shows that most patients with severe cutaneous adverse reactions had SCORTEN scores of 2–3, accounting for 36.4% and 27.3% of patients, respectively. A score of 0–1 was

observed in 27.3%, while only 9.1% had a score of 4. No patient had a SCORTEN score ≥5, indicating that the highest predicted mortality category was not observed in this study.

Table IV

SCORTEN scores among patients with severe cutaneous adverse reactions (n=11).

SCORTEN score	Predicted mortality (%)	n	%
0–1	3.2 – 12.1	3	27.3
2	16.2	4	36.4
3	26.4	3	27.3
4	42.1	1	9.1
≥5	≥57.0	0	0.0

Note: Mean SCORTEN score among patients with SJS, TEN, DRESS, and AGEP was 2.4 ± 1.1 , corresponding to a predicted mortality of 18.4%.

Table V shows a significant association between anticonvulsant use and SJS/TEN (p=0.004). Anticonvulsants were used in 5 (55.6%) patients with SJS/TEN compared with 4 (10.5%)

without SJS/TEN, while other drugs accounted for 4 (44.4%) and 34 (89.5%), respectively. Thus, anticonvulsant use was significantly more common among patients with SJS/TEN.

Table V

Association between anticonvulsant use and severe cutaneous adverse reactions (SJS/TEN).

Drug class	SJS/TEN		p-value
	Present	Absent	
	(n=9) n (%)	(n=38) n (%)	
Anticonvulsants	5 (55.6)	4 (10.5)	0.004
Other drugs	4 (44.4)	34 (89.5)	

p-value was derived using Fisher's exact test.

DISCUSSION

This prospective cohort study evaluated the spectrum of cutaneous adverse drug reactions among 47 adult patients in a tertiary care hospital in Bangladesh. The findings demonstrate that morbilliform exanthema is the most frequent clinical pattern, antibiotics are the leading causative drug class, and anticonvulsants are significantly associated with severe cutaneous adverse reactions. The predominance of morbilliform exanthema (34.0%) in our cohort is consistent with established evidence that morbilliform eruptions are the most common cutaneous drug reactions, accounting for approximately 28–34% of all CADR [1]. Urticarial reactions

(21.3%) and fixed drug eruptions (17.0%) were the next most frequent patterns in our study, which aligns with previously reported frequencies [6]. The relatively lower proportion of severe reactions (SJS/TEN: 12.8%) in our cohort compared to some tertiary care settings may reflect the inclusion of both outpatient and inpatient cases, whereas previous studies focusing exclusively on severe reactions have reported higher proportions [3]. Antibiotics were the most commonly implicated drug class, accounting for 44.7% of cases in our study. This finding corroborates a systematic review reporting that antimicrobials constitute the majority of causative agents in CADR [4]. Among antibiotics, cephalosporins, penicillins, and

quinolones have been identified as the most common triggers for severe cutaneous adverse reactions [10]. Anticonvulsants were the second most frequent class (19.1%) in our cohort, which is consistent with previous reports where anti-epileptic drugs accounted for a substantial proportion of CADR [9]. The significant association between anticonvulsant use and SJS/TEN observed in our study (55.6% vs. 10.5%, $p=0.004$) aligns with established evidence that lamotrigine, carbamazepine, and phenytoin carry the highest risk for severe cutaneous reactions [11]. The risk of SJS/TEN following initiation of antiseizure medications is particularly elevated for lamotrigine and carbamazepine, necessitating vigilant monitoring and, in certain populations, genetic screening for HLA-B 15:02 alleles [12]. The Naranjo adverse drug reaction probability scale assessment revealed that the majority of patients (51.1%) had probable causality, followed by possible (36.2%) and definite (12.8%) causality [14]. This distribution is comparable to previous studies where the Naranjo scale yielded similar proportions of probable and definite cases [16]. The absence of doubtful cases in our cohort reflects the rigorous clinical evaluation and comprehensive drug history taken by the consultant dermatologist. The Naranjo scale, despite its limitations in polypharmacy settings, remains a practical and accessible tool for causality assessment in clinical practice [14]. Among patients with severe cutaneous adverse reactions (SJS, TEN, DRESS, and AGEP), the mean SCORTEN score was 2.4 ± 1.1 , corresponding to a predicted mortality of 18.4% [15]. This finding is consistent with the reported mortality range of 10–40% for SJS and TEN [8]. The SCORTEN scoring system, validated in multiple populations, incorporates seven prognostic parameters to predict in-hospital mortality and is significantly associated with mortality outcomes [15]. However, the SCORTEN score may have limitations across different populations, and elevated serum creatinine has been suggested to enhance risk prediction [17]. The relatively lower mortality observed in our cohort compared to some Western studies may reflect differences in patient demographics, disease severity at presentation, or availability of intensive care support [18]. The clinical implications of our findings are substantial. Prompt recognition and withdrawal of the offending drug remain the cornerstone of CADR management [2]. For mild to moderate reactions, symptomatic treatment with oral antihistamines and topical corticosteroids is usually sufficient [5]. However, for SCARs including SJS, TEN, and DRESS, early identification, immediate drug cessation, and multidisciplinary supportive care in specialized burn or intensive care units are critical to reducing morbidity and mortality [13]. The updated European guidelines for the management of SCARs recommend systemic corticosteroids, intravenous immunoglobulins, or cyclosporine in severe cases, although evidence remains limited [19]. In resource-limited settings such as Bangladesh, the implementation of such measures faces significant challenges, including limited awareness, inadequate pharmacovigilance infrastructure, and economic constraints [13,20]. Nevertheless, our data emphasize the need for strengthened pharmacovigilance programs, enhanced dermatological training for primary care physicians, and accessible specialized care for patients with severe cutaneous adverse drug reactions.

LIMITATIONS

The single-center design, purposive sampling strategy, small sample size, absence of confirmatory patch testing, and reliance on self-reported drug history limit generalizability and preclude definitive causal attribution of our findings.

CONCLUSION

Cutaneous adverse drug reactions in Bangladeshi adults demonstrate a diverse clinical spectrum, with morbilliform exanthema being the most common pattern. Antibiotics are the leading causative agents, while anticonvulsants are significantly associated with severe reactions including SJS and TEN. Prompt recognition, early drug withdrawal, and strengthened pharmacovigilance programs are essential to reduce morbidity and mortality.

RECOMMENDATION

We recommend strengthening pharmacovigilance programs, implementing systematic adverse drug reaction reporting systems, promoting awareness among clinicians, and establishing specialized dermatology units for early recognition and multidisciplinary management of severe cutaneous adverse drug reactions in Bangladesh.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest. No funding was received for this study. The corresponding author had full access to all data and final responsibility for the decision to submit for publication.

AI DECLARATION

Artificial intelligence tools contributed marginally to manuscript preparation and development. All core scientific content was human-verified.

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